

What is claimed is:

1. A solid crystalline ondansetron having at least one of the following characteristics:
 - a melting endotherm peak greater than or equal to 240°C;
 - a trace amount of a base or residue thereof comprising an alkali metal, an amine, an ammonium or an ion thereof; or
 - a water content of 1.3 to 1.5 wt%.
2. The ondansetron according to claim 1, wherein said ondansetron has a first melting endotherm peak greater than or equal to 240°C.
3. The ondansetron according to claim 1, which is form II ondansetron.
4. The ondansetron according to claim 3, which was formed by precipitating said solid crystalline ondansetron from a solution at a temperature greater than or equal to 40°C.
5. The ondansetron according to claim 1, wherein said ondansetron has a powder x-ray diffraction pattern that substantially corresponds to figure 6.
6. The ondansetron according to claim 1, wherein said ondansetron contains a trace amount of a base or residue thereof which comprises an alkali metal, an amine, an ammonium, or an ion thereof.
7. The ondansetron according to claim 6, wherein said base or residue is contained in an amount of from 1 ppm to 1000 ppm.
8. The ondansetron according to claim 7, wherein said base or residue comprises an ion of an alkali metal.
9. The ondansetron according to claim 8, wherein said alkali metal is sodium.
10. The ondansetron according to claim 1, wherein said ondansetron is a hydrate.
11. The ondansetron according to claim 10, comprising ondansetron and water wherein the amount of water relative to ondansetron is within the range of 0.23-0.27 moles per each one mole of ondansetron.

12. The ondansetron according to claim 11, wherein the amount of water is within the range of 0.24 to 0.26 moles per each one mole of ondansetron.
13. The ondansetron according to claim 1, wherein said ondansetron has a water content of 1.3 to 1.5 wt%.
14. The ondansetron according to claim 2, wherein said ondansetron has a water content of 1.3 to 1.5 wt%.
15. A crystalline ondansetron base having a purity of at least 98% and being in the form of particles wherein at least 99% of the particles have a particle size within the range of 0.1 to 63 microns.
16. The ondansetron according to claim 15; wherein at least 99% of the particles have a particle size less than 10 microns.
17. The ondansetron according to claim 15, wherein 90% said particles have a size of 2 microns or less.
18. A composition comprising the ondansetron according to claim 1 and a pharmaceutically acceptable excipient.
19. The composition according to claim 18, wherein said composition is a unit dose form.
20. The composition according to claim 19, wherein said ondansetron is contained in an amount of 0.1 to 150 mg.
21. The composition according to claim 20, wherein said amount of ondansetron is 1, 2, 4, 8, 16, or 24 mg.
22. A process, which comprises:
 - neutralizing an acid addition salt of ondansetron to liberate ondansetron free base; and
 - precipitating said ondansetron free base from a liquid media.
23. The process according to claim 22, wherein said precipitated ondansetron is form I ondansetron.

24. The process according to claim 23, wherein said neutralization and precipitation is carried out in one liquid phase.
25. The process according to claim 24, wherein said liquid phase comprises a solvent selected from the group consisting of a C₁-C₆ aliphatic alcohol, C₁-C₆ aliphatic ketone, C₃-C₆ cyclic ether, water, or mixtures of two or more thereof.
26. The process according to claim 24, wherein a contra-solvent is added to said liquid phase after said neutralization step in order to assist said precipitation step.
27. The process according to claim 23, wherein said neutralization is carried out in a first liquid phase and said precipitation is carried out in a second liquid phase.
28. The process according to claim 23, wherein said precipitated ondansetron has an average particle size of 20 microns or less.
29. The process according to claim 23, which further comprises converting crude ondansetron base into said acid addition salt of ondansetron, optionally followed by isolation of said salt before said neutralizing step.
30. A process, which comprises dissolving ondansetron free base in a solvent and precipitating said dissolved ondansetron free base to form ondansetron having a melting endotherm peak of greater than or equal to 240°C.
31. The process according to claim 30, wherein said precipitated ondansetron is form II ondansetron.
32. The process according to claim 31, wherein said precipitation occurs at one or more temperatures greater than 40°C.
33. The process according to claim 31, which further comprises contacting said solvent containing said dissolved ondansetron with activated charcoal prior to said precipitating step.